

**SOP#: ADCR-13**

**Clinical Center External Location Registration**

**Version #: 2.0**

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**NCI Clinical Director Signature:**

## **POLICY**

Any participant who consents to an NIH protocol needs to have a medical record number prior to signing the consent document. For some protocols, the IRB will approve a phone consenting process as the participant may not initially, or ever, travel to the NIH. For these situations, the NIH Clinical Center (CC) allows for research participant registration from an external site.

This process is to be used for the following:

- Acquire biospecimen: This may be done as part of a separate tissue acquisition protocol or as part of an intervention protocol that allows telephone consenting.
- Eligibility criteria that require NIH/NCI pathology confirmation or official radiology read of scans: This would include requesting blocks/slides from an outside pathology department or requesting a CD for official read from an outside radiology department.
- Any other procedure (e.g., HLA typing, etc.) that will take place prior to a research participant coming to the Clinical Center.

The external location registration process may be completed by the Research Nurse Coordinator (RNC) or Patient Care Coordinator (PCC).

## **PURPOSE**

The purpose of this standard operating procedure is to provide instructions for external site research participant registration with the NIH Clinical Center including appropriate documentation of the process.

## **RESOURCES**

- Health Information Management Department (HIMD) [External Location Registration Resources and Forms](#)
- Patient Travel [Toolkit](#)
- Admissions, Travel and Vouchers (ATV) [website](#) and [Quick Reference Guides](#)
- EXT-LOC Process webinar recording – located on the CCR SOP [website](#)

## PROCEDURES

### STEP 1: Gather the Required Forms

**Note:** These forms cannot be modified. No crossing out of words or phrases or rewriting language on the form.

Forms can be found on the HIMD website referenced above.

#### Adults

- Research Participant Registration EXT-LOC Demographics Form (Form PSSD EXT LOC: *Research Participant Registration Form, External Location*): Spanish version available
- EXT-LOC Registration Consent (Form NIH-1225-4: *Consent to External Location Registration for the NH Clinical Center*); Spanish version Form NIH-1225-4-SP
- EXT-LOC Notice and Acknowledgement of Info Practices (Form NIH-2753: *Notice and Acknowledgement of Information Practices*); Spanish version Form NIH-2753 -SP
- EXT-LOC Consent - Authorization for Electronic Communications (Form NIH-2984: *Authorization for Electronic Communications and Communication with Outside Healthcare Providers*); Spanish version Form NIH-2984-SP

#### Pediatrics

**NOTE:** See Step 1a below before completing pediatric external location registration

- Research Participant Registration EXT-LOC Demographics Form (Form PSSD EXT LOC: *Research Participant Registration Form, External Location*): Spanish version available
- EXT-LOC Registration Consent (Form NIH-1225-4: *Consent to External Location Registration for the NH Clinical Center*); Spanish version Form NIH-1225-4-SP
- EXT-LOC Notice and Acknowledgement of Info Practices (Form NIH-2753: *Notice and Acknowledgement of Information Practices*); Spanish version Form NIH-2753 -SP
- EXT-LOC Consent - Authorization for Electronic Communications (Form NIH-2984: *Authorization for Electronic Communications and Communication with Outside Healthcare Providers*); Spanish version Form NIH-2984-SP
- EXT-LOC Statement of Relationship to Child (Required to determine relationship to child and if there is a sole or joint custody arrangement or person is not a legal guardian) (Form NIH 2812: *Statement of Relationship to Child*); Spanish version Form NIH-2812-SP

### STEP 1a: For Pediatric Participants: Determining Parent/Legal Guardian

- The RNC/team needs to determine what the family structure is before external location registration can proceed.
- If parents are married to each other, only one parent needs to sign admission paperwork. Minor participant does NOT sign paperwork.
- Scenario 1: If the biological or adoptive parents are divorced or legally separated and if there is sole or joint custody court document for medical decision making, the court documents\* will need to be sent via secure email to CC Admissions at [CCAdmissionsLeadership@cc.nih.gov](mailto:CCAdmissionsLeadership@cc.nih.gov).
  - CC Admissions will forward to NIH Office of General Counsel (OGC) to determine if only one or both parents have to sign Admissions documents.

- Scenario 2: If the biological parents are not married but have sole or joint custody court document for medical decision making, follow scenario 1. If there is no custody court document, then contact admissions to determine if one or both parents need to sign.
- Scenario 3: If participant has a legal guardian, the court guardianship documents\* will need to be sent via secure email to CC Admissions at [CCAdmissionsLeadership@cc.nih.gov](mailto:CCAdmissionsLeadership@cc.nih.gov).
  - CC Admissions will forward to NIH Office of General Counsel (OGC) to determine if the guardian can sign the Admissions documents.
- Once it is clear\* who the appropriate Legally Authorized Representative(s) (LAR) is, proceed to step 2.

**Note:** Allow at least 3 days for review by OGC.

\*If court documents for medical decision making cannot be located, both parents will be asked to sign all admission paperwork. They can sign on same form or separate forms. Minor participant does NOT sign paperwork.

## STEP 2: Form Review and Completion

- Send the blank forms to the participant/LAR via fax, email or mail.
- Once the participant/LAR has received the documents, the RNC or PCC should review all the forms with him/her and instruct him/her on how to complete and return the forms.
  - Forms may be returned via secure fax, by mail, or by email using the Secure E-mail and File Transfer Service (SEFT) – See Appendix A.

Please note that several of the forms require a signature of witness. The witness must observe the participant/LAR sign the form and must use the same date that the participant/LAR uses to sign the form.

- *Research Participant Registration Form, External Location* form may be completed by the RNC/PCC. The participant/LAR doesn't need to sign this form. All fields in the "Patient Information" section are required to be completed. In the "Contact Information" section, complete fields for at least one person. If a pediatric participant, complete second parent/guardian information if required.

Please note that this is the required legal order for the contact person information; Admissions will return the form if it is not done correctly:

- 1) Spouse or domestic partner
- 2) Adult children
- 3) Parents
- 4) Brother or sister
- 5) A distant relative

The second page on this form is optional EXCEPT for the last two lines ("Information provided by" and "Relationship to patient").

**IMPORTANT:** Ensure that the **legal, complete name is spelled correctly**, and the date of birth is accurate.

- Review with participant/LAR the *Consent to External Location Registration for the NIH Clinical Center* form:
  - Remind the participant/LAR to sign all appropriate places and his/her signatures must be legible. Date of signature is required.
  - Signature of Witness is required to attest that the participant/LAR signed the document. The date that the witness signs must match the date that the participant/LAR signs.
  - Once the signed form has been returned (via fax, secure email or mail), the NIH staff/contractor that reviewed the consent with the participant/LAR must complete the bottom portion below “Official Use only Below This Line.” The signature date is the date the form is returned and reviewed.
- Review the *Notice and Acknowledgement of Information Practice* form:
  - Review with participant/LAR who will have access to medical record information.
  - Remind the participant/LAR to sign all appropriate places and his/her signatures must be legible. Date of signature is required.
  - Signature of witness is required to attest that the participant/LAR signed the document.
- Review *Authorization for Electronic Communications and Communication with Outside Healthcare Providers* form:
  - Discuss email communication and if they would like to do that, make sure they know to check the box at the bottom of the page, provide their email address and sign an additional time at the bottom of the form. This is where they select to have secure communication via email.
  - Remind the participant/LAR to sign all appropriate places and that all signatures must be legible. The participant/LAR needs to provide a witness to his/her signature.
- All forms must be reviewed for completeness and accuracy; work with the participant/LAR to ensure accuracy and completeness.

### **STEP 3: Admission Travel Voucher (ATV) Entry**

- Once all forms are complete, enter an ATV Admission request to obtain an MRN.  
Note: insert in Remarks Section “off-site registration.”
  - New participants can be entered as EXT LOC: select “Patient will be seen at External Location”
- Print the *Electronic Admission Request* from the Admission/Travel/Voucher (ATV) system.
- See Admissions, Voucher and Travel (ATV) website for more information.

#### **STEP 4: Informing CC Admissions Office**

- Once the ATV request has been submitted, provide the ATV request and all the completed/signed forms/consents to Admissions. This can be done either via secure fax (301-402-0664) or hand delivery. If sending by fax, please call and confirm receipt.
  - Forms can also be sent via secure e-mail to [CCAdmissionsLeadership@cc.nih.gov](mailto:CCAdmissionsLeadership@cc.nih.gov)

**NOTE:** If this step is not done, participant stays in pre-admit status.

- If the ATV form is sent electronically prior to Admissions receiving the packet of completed forms, please write in the Remarks Section “Off-site labs only – consents will be sent to Admissions.”
- The participant’s information will be entered into CRIS that evening and placed in a pre-admit status. The research participant will not be activated or officially admitted in CRIS until all the completed forms have been given to Admissions.
- The date of Admission (Outpatient Registration) will be the date the consent forms are received by CC Admissions.

#### **STEP 5: Protocol Specific Consent Process/Documentation**

- Obtain the informed consent document for the specific study.
- Consent via phone as per IRB approved protocol.
- Remind the participant/LAR to legibly print name and sign all appropriate places. Note: Signatures must be legible.
- If English speaking, the participant/LAR does not need to provide a witness to their signature.
- Investigator documents consent process note in CRIS using the Informed Consent structured progress note entitled “Documentation of Consent.”
- Once the signed consent is returned, the Investigator can print, sign and date (using the date of receipt of the consent).
- Investigator completes consent process note in CRIS using the Informed Consent structured progress note entitled “Documentation of Consent.”
- Send the signed protocol consent documents to HIMD for upload into CRIS.

#### **STEP 6: Document Sample(s)/Scans Received**

- Obtain/request samples/scans per protocol.
- Document sample/scan acquisition in CRIS using “External Location Registration Note”
  - This note can be found under the “Documents.”
  - This allows you to document information about the sample(s) received. Participant will remain in EXT LOC status.
  - You do NOT need a co-signature on this note.

## Appendix A

### Instructions for Using Secure E-mail and File Transfer Service (SEFT)

The NIH provides a service that allows secure transfer of personally identifiable information (PII) from/to individuals outside the Department of Health and Human Services email network. Using the Secure E-mail and File Transfer Service (SEFT) ensures the protection of PII such as social security numbers, birth dates, and thoroughly secures all data and information being sent via email.

Any correspondence with prospective participants that requires transfer of PII is required to use SEFT to encrypt the email and attachments. When an email is sent to a prospective participant via SEFT, the prospective participant will receive an email with a link to the SEFT site and the specific email.

For more information about SEFT, please see:

<https://emib.cit.nih.gov/services/Pages/secureFiletransfer.aspx>

#### Step 1: Access SEFT

- If this is the first time using SEFT, you must first request access from the NIH IT Service Desk: 301-496-4357 (or there is an online request that can be accessed via the above website).
- Access the SEFT login page via: <https://secureemail.nih.gov/bds/Login.do>. Sign in with NIH domain account username and password. Type "NIH/" prior to the username per instructions on SEFT login page.

#### Step 2: Compose secure email

- Select "Compose Delivery" to access a new secure message email template. Files can also be uploaded.
- Once an email is sent, the recipient can be added to a "Contacts" list.

#### Step 3: Prospective participant receives email notification

- The prospective participant will receive an email with a link directly to the secure email information and any attachments via the SEFT website.
- If this is the first time using SEFT, the prospective participant will need to register with the SEFT system.

**Note:** The person sending the email will receive an email from SEFT that the secure email has been viewed by the prospective participant.

**Step 4: Prospective participant can respond to the email via SEFT**

- Prospective participant can send copies of scanned completed registration documents securely via SEFT.

**Note 1:** An email address external to NIH/HHS cannot send an email that starts an email chain. They can respond to an email sent from SEFT, including attaching documents.

**Note 2:** Attachment size is limited to 2MB. If document size is too large, the document will need to be separated and sent as multiple emails.

**Step 5: Download attachments**

- Research team should download attachments and save to a secure computer location for sending to the Admissions Office per Step 4 above.

**Note:** Emails are only kept for 90 days in the SEFT then deleted.